REMARKS

Applicant wishes to thank Examiner Nathan Bowers for the informative interview extended to Applicant's representative on February 7, 2008 (the "Interview"). New claims 40-42 are added. Claims 1-3, 5-11, 16-24, 38, and 40-42 are currently pending. In view of the amendments and the remarks below, Applicant respectfully asserts the pending claims are now in condition for allowance, and requests all claim rejections be withdrawn and the claims be allowed.

New and Amended Claims

Claims 1, 3, and 38 are amended as illustrated in the foregoing section **Amendments to the Claims**. Dependent claims 40-42 are added by this paper. The amendments and new claims do not add new matter because support for the amendments and new claims can be found in the application as filed. *See* Figures 1, 2, and 7, and paragraphs 0023, 0033, 0042 and 0059 of the application (as filed) for examples of support for the amendments and new claims.

Discussion of the Claim Rejections Under 35 U.S.C. § 103

In the Office Action, the Examiner rejected claims 1-3, 5-11, 16-20, 23, 24 and 38 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,385,496 ("Irwin"), in view of U.S. Publication No. 2005/0186671 ("Cannon") and European Patent Publication No. EP 0156176 ("Zeitlin"). The Examiner also rejected claims 21 and 22 under 35 U.S.C. § 103(a) as being unpatentable over Irwin in view of Zeitlin as applied to claim 9, and further in view of U.S. Patent No. 6,048,721 ("Armstrong").

Applicant respectfully traverses the above-listed section 103 rejections and submits that the cited art does not establish prima facie obviousness of a claimed invention because all the claim limitations are not taught or suggested by the prior art, as required. *See* M.P.E.P § 2143.03.

Claim 1 (amended herein) recites a system for controlling bioreactors where the system comprises "a first communication network; a second communication network;" a first and second bioreactor; "a utility tower housed separately from said first and second bioreactors and configured to sense conditions in said first and second bioreactors and provide services to said first and second bioreactors" and configured to send information over the first communication

network and receive signals over the second communication network; and a controller connected to the utility towers by the first and second communication networks.

As claim 1 recites, the utility tower is housed separately from the bioreactors and is configured to provide services to the bioreactors. The separate housing for the utility tower allows the utility tower to be located away from the bioreactors and may allow for multiple bioreactors to be connected to a single utility tower. The separate housing may also allow replacement of a bioreactor attached to the utility tower. Also, the utility tower may send information to and receive signals from the controller over a first and second communication network, thereby providing an efficient and cost-effective way to communicate information.

As discussed in the Interview, in addition to communicating information as claimed, the utility tower also "provides services to said first and second bioreactors that affect the conditions in said first and second bioreactors." Such services may include adding or removing a fluid, gas, or solid. *See, e.g.*, paras. 0032 and 0033 of the application as filed. Such services may also include changing or controlling the pH or temperature of the contents of a bioreactor, among other services. *See, e.g.*, paras. 0044, 0047, and 0050 of the application as filed.

In paragraph 1 of the Office Action, the Examiner states that "Irwin, however, does not expressly indicate that a utility tower is used to transmit detected conditions within the reactors to the controller." Thus, Irwin does not teach a utility tower housed separately from bioreactors that provides services to the bioreactors and that sends information to and receives signals from a controller over a first and second communication network, respectively.

Cannon is generally directed to cartridges providing a closed-loop flowpath for bio-cultures contained therein. *See Cannon*, abstract and para. 0013. The cartridges can be integrated into an incubating rack. *Id.* Each cartridge may contain a local controller, a bioreactor, and an amplifier or transmitter to transmit information from the bioreactor to the local controller. *See Cannon*, paras. 0058 and 0083. In the Office Action, the Examiner states that "Cannon teaches in paragraph [0083] that data obtained by each of the sensors in each of the bioreactor assemblies is first sent to a utility tower in the form of an amplifier or a transmitter, and then it is sent a controller via a communication path or bus." Cannon, however, discloses that the amplifier or transmitter is located within the same cartridge as the bioreactor and the local controller. The amplifier or transmitter is not separately housed and can only send

information to the local controller; the amplifier or transmitter does receive signals over a second communication network. Additionally, the amplifier or transmitter does not provide any services to the bioreactor, as recited in claim 1. Accordingly, Applicant respectfully submits that Irwin does not teach or suggest the claimed utility tower housed separately from the bioreactors and providing services to the bioreactors, and communicating with a controller over a first and second communication network.

Applicant respectfully submits that these limitations are also not taught or suggested by Zeitlin. Zeitlin is generally directed to a system for controlling fermentation units. The system contains a local direct digital controller **10** to operate each fermentation unit **15**. *See Zeitlin*, page 7. Each controller has a microprocessor **45** that runs the fermentation process for the fermentation unit **15**. *See Zeitlin*, page 6. Zeitlin does not disclose a utility tower housed separately from the fermentation units that provides services to the fermentation units, nor does Zeitlin disclose that such a utility tower could communicate with a controller over a first and second communication network, as claimed. Additionally, Armstrong does not cure the deficiencies of Irwin or Zeitlin.

Independent claims 3 and 38 also recite a similar configuration as in claim 1 for the utility tower and the controller, and at least a first and second communication network. Accordingly, Applicant respectfully submits that the cited references fail to teach or suggest at least one limitation from each of claims 1, 3, and 38, and submits that the claims are in condition for allowance for at least the reasons stated above.

Dependent claims 2, 5-11, and 16-24 depend directly or indirectly from claims 1 and 3, and therefore Applicant respectfully asserts claims 2, 5-11, and 16-24 are also in condition for allowance for at least the same reasons, and requests the section 103 rejections be withdrawn.

Commercial Success Of The BioNet® Product Illustrates The Invention Is Non-obvious

Applicant respectfully asserts that the commercial success of Broadley-James' bioreactor control system product "BioNet®" illustrates the invention and the pending claims are nonobvious over the cited art. The Supreme Court deemed evidence of (1) commercial success and (2) some causal relation or 'nexus' between an invention and commercial success of a product embodying

that invention, probative of whether an invention was non-obvious. *See* Graham v. John Deere Co., 383 U.S. 1, 17-18 (1966). *See* MPEP 716.03.

Broadley-James is the assignee of the above-captioned application, and currently manufactures and sells "BioNet®," a bioreactor control system product. BioNet® embodies the technology of the invention, including the subject matter of one or more of the pending claims in the above-identified application (see Declaration of Scott T. Broadley ¶¶ 1 and 4, attached hereto). Broadley-James began investigating automated bioreactor controls at least as early as November 2001. At that time, the existing bioreactor control systems often required manual intervention even during normal operation. When Broadley-James began its development, there were no bench-top automated bioreactor control systems that included the features claimed in the '168 application, nor any systems like BioNet®. Decl. Broadley ¶ 4.

Throughout 2002 and 2003, Broadley-James developed and tested bioreactor control system configurations and refined its BioNet® product. Broadley-James invested many man-years and hundreds of thousands of dollars developing and building BioNet®, an automated bioreactor control system. BioNet® includes a uniquely configured utility tower and controller which provide all services to a bioreactor (e.g., for cell growth), and a communication network connecting the utility tower and the controller. Decl. Broadley ¶ 4.

Configurations of BioNet® include the same features described in the '168 application, for example, a first and second communication network, and a controller and a utility tower with configurations as recited in the pending claims and as described in the above-captioned application. At the time of the invention, these features were unique to BioNet®. Decl. Broadley ¶ 5.

Broadley-James did not manufacture or sell any automated bioreactor control systems prior to developing BioNet®. Instead, Broadley-James sold instrumentation such as pH probes and other equipment for use in fermentation or cell growth chambers. Cell-growth technology is extremely complex, and bioreactor control systems are applicable only to a niche market with a limited number of potential customers. However, despite entering into a brand new area of business that has a relatively small potential market, Broadley-James achieved immediate commercial success with BioNet®, largely due to its unique utility tower and controller features and configuration, the same features and configurations as claimed and described in the '168

application. BioNet® sales have increased dramatically, as shown by the invoiced amounts for BioNet® projects during the past five calendar years:

(2002: no sales)

2003: $ 544,322.30

2004: $ 1,240,464.40

2005: $ 3,173,004.81

2006: $ 3,116,941.84

2007: $ 6,556,535.00

Decl. Broadley ¶ 6.

BioNet® was an "overnight" commercial success. To date, Broadley-James has invoiced more than $14,631,266 for its BioNet® product. To provide context to this data, between about September 2006 and September 2007, Broadley-James's BioNet® product accounted for about 30-50% of the market share for these types of control systems. Broadley-James became a market leader with cumulative sales of over $14 million in just a few years. BioNet® captured the industry's attention and over 30% market share in just five years because customers recognized the commercial benefits of its uniquely configured utility tower, controller and communication network, the same features claimed in the '168 application, and in each bioreactor system sold. *See Hybritech Inc. V. Monoclonal Antibodies Inc.*, 802 F.2d 1367, 1382 (Fed. Cir. 1986), 231 USPQ 81, 92 (finding commercial success supported a conclusion of nonobviousness where patentee's product became a market leader with 25% of the market and over $20 million in sales in just a few years). Decl. Broadley ¶ 7.

After seeing the commercial success of BioNet®, Broadley-James' competitors have begun to emerge with their own bioreactor control products. These other companies often compare their products to BioNet® and/or discuss Broadley-James BioNet® system in their marketing material. Decl. Broadley ¶ 7.

Widespread advertising is *not* the reason for the success of BioNet®. Because of its limited and highly specialized market, a bioreactor controller is not the type of product that can be easily sold through wide-spread advertising. Instead, Broadley-James relies on trade show demonstrations, selective industry advertising, and specifically directed customer interaction to sell BioNet®. The commercial success of BioNet® is not due to an extensive marketing

campaign, but instead, as a result of its innovative and unique utility tower, controller, and communication network configuration which offers customers a flexible, cost-effective and scalable solution for benchtop bioreactor control. Decl. Broadley ¶ 8.

Accordingly, for at least the reasons of achieving millions of dollars in sales and a dominant (at least) 30% market share in just a few years without extensive advertising, Applicant respectfully asserts that the remarkable commercial success of BioNet® rebuts the Examiner's assertion of non-obviousness as stated in the Office Action, and requests the section 103 rejections be withdrawn.

Nonstatutory Obviousness-Type Double Patenting

The Office Action indicates Claims 1-24 and 38 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting (ODP) as being unpatentable over claims 1-4, 8-11, 14-22, 27 and 40-48 of copending application No. 11/057079. The above-captioned application is the earlier of the two co-pending applications. Applicant respectfully asserts that the pending claims in the above-captioned application are now in condition for allowance in light of the previously presented amendments and/or arguments. Accordingly, Applicant respectfully requests the Examiner to withdraw the ODP rejection permitting the earlier filed application to issue as a patent without a terminal disclaimer. See MPEP §1490V(D).

Discussion of Blevins

In the interview, the Examiner introduced U.S. Patent No. 7,110,835 ("Blevins"). Applicant respectfully submits that at least the above recited limitations are also not taught or suggested by Blevins.

Blevins is generally directed to integrating process and display modules in a system to provide simulation and control of the system. See Blevins, abstract. A controller **12** implements a control strategy in field devices **14** or **16**, and modules or function blocks **30** in field devices **14** or **16** may be executed according to the control strategy. See Blevins, col. 6, line 61 – col. 7, line 3. Blevins discloses the field devices **14** or **16** are typically distributed throughout a plant environment and can be sensors, valves, transmitters, or positioners. See Blevins, col. 6, lines

24-31, col. 7, lines 8-13. The function blocks **30** may be executed in conjunction with control modules **29** within the controller **12**.

The system disclosed in Blevins does not teach or suggest all of the limitations of the pending claims, nor does Blevins cure disclosure deficiencies of Irwin, Cannon, Zeitlin, and Armstrong. For example, Blevins also does not teach or suggest a separately housed utility tower that can provide services to a bioreactor. Instead, Blevins discloses a general control system comprising a controller **12** and field devices **14** or **16** that are distributed throughout a plant environment on various pieces of equipment, not in a utility tower configuration. Additionally, Applicant respectfully submits that the field devices **14** or **16** cannot be equated with the utility tower recited in Claim 1. The field devices **14** or **16** are described as single devices, such as a sensor, transmitter, or valve. However, Blevins does not disclose that any of the field devices function as a utility tower, sensing conditions in an attached bioreactor and provide services to the bioreactor as recited in Claim 1. In addition, there is no teaching that the field devices **14** or **16** communicate with the controller **12** over a first and second communication network. Thus, Applicant respectfully submits that Blevins does not teach or suggest a separately housed utility tower, as claimed, that provides services to bioreactors and communicates with a controller over a first and second communication network.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, the Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. The Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

Conclusion

The applicant has endeavored to address all of the Examiner's concerns as expressed in the outstanding Office Action. In view of the foregoing amendments and remarks, Applicant respectfully requests reconsideration and withdrawal of the outstanding rejections, and that the claims now be found in condition for allowance.

Any claim amendments which are not specifically discussed in the above remarks are not made for patentability purposes, and it is believed that the claims would satisfy the statutory requirements for patentability without the entry of such amendments. Rather, these amendments have only been made to increase claim readability, to improve grammar, and to reduce the time and effort required of those in the art to clearly understand the scope of the claim language. No new matter has been added by any of the claim amendments as disclosure relating to any of the amendments can be found in the specification and claims as originally filed.

Should the Examiner have any remaining concerns that might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number below.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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